

(6) Agreement to be bound by the DHHS rules involving the use of human and animal subject, and human tissue.

(7) Ability to obtain background license to relevant patent rights.

(8) Willingness to agree to Federal Statutory provisions for the equitable distribution of patent rights to any CRADA subject-matter inventions. Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (A) an irrevocable, non-exclusive, royalty-free research license to the Government (when a company employee is the sole inventor) or (B) an option for an exclusive or non-exclusive license to the company on terms that are appropriate (when the Government employee is the sole or joint inventor).

(9) Willingness to cost share in laboratory studies including the funding of personnel dedicated to completion of the CRADA research project.

(10) Submission of an initial response to the NIH Model CRADA boilerplate provisions.

Dated: April 13, 1995.

Dr. Thomas Mays,

*Director, Office of Technology Development,
National Cancer Institute, National Institutes
of Health.*

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**National Cancer Institute: Opportunity
for a Clinical Trial Cooperative
Research and Development Agreement
(Clinical Trial "CRADA") for the
Scientific and Commercial
Development of the Signal
Transduction Inhibitor, "CAI", as an
Anticancer Agent**

AGENCY: National Institutes of Health,
PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a pharmaceutical company which can effectively pursue the clinical development of the signal transduction inhibitor, carboxamide-amino triazole ("CAI", NSC 609974), for the treatment and/or prevention of cancer. The National Cancer Institute has data suggesting that CAI may have potential for the treatment and prevention of cancer. The selected sponsor will be awarded a CRADA for the co-development of this agent with the National Cancer Institute.

ADDRESSES: Questions about this opportunity may be addressed to Mark W. Noel, Office of Technology Development, NCI, Building 31/Room 4A51, 9000 Rockville Pike, Bethesda,

Maryland 20892, (301) 496-0477, facsimile (301) 402-2117, from whom further information including a summary copy of the preclinical and clinical data may be obtained.

DATES: In view of the important priority of developing new agents for the treatment or prevention of cancer, interested parties should notify this office in writing no later than June 25, 1995. Respondents will then be provided an additional 60 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION:

"Cooperative Research and Development Agreement" or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below. The present opportunity will be for a Clinical Trial CRADA. The Clinical Trial CRADA is a modification of the standard NIH Model Agreement wherein additional language has been drafted to enable the Collaborator to access and utilize clinical trial data.

The Government is seeking a pharmaceutical company which, in accordance with the requirements of the regulations governing the transfer of agents in which the Government has taken an active role in developing (37 CFR 404.8), can further develop CAI through Federal Food and Drug Administration approval and to a commercially available status to meet the needs of the public and with the best terms for the Government.

CAI is a novel chemically defined compound which has shown promising antitumor activity in several preclinical trials. The drug is under patent to Merck & Co., Inc. (U.S. Patent 4,590,201). The use of CAI in a method of treating peritoneal carcinomatosis of solid tumors is claimed in U.S. Patent 5,132,315 assigned to the Dept. of Health and Human Services. A method for the detection and quantitation of CAI levels in blood is claimed in U.S. Patent 5,405,782 which is also assigned to the Dept. of Health and Human Services. Its use in the treatment of cancer in patients with a surgically excised tumor with a high probability of metastasis and its use in treatment of cancers involving the transportation of individual cells to other tissue from a metastasizing tumor are claimed in U.S. Patent 5,045,543 (assigned to Merck & Co. Inc). The Clinical Trial CRADA will allow a pharmaceutical company to provide resources, in collaboration with the NCI, for the continuing preclinical and clinical development work for this

agent and its eventual commercialization. Merck & Co.'s patent rights will be available for licensing on terms to be mutually agreed upon by Merck and the selected Collaborator. Similarly, the Government will make its relevant intellectual property rights available for licensing to the Collaborator.

Based on the promising data obtained from the ongoing Phase I clinical trials, there is a need to obtain greater quantities of CAI and to continue clinical development of this agent. The NCI is interested in establishing a Clinical Trial CRADA with a pharmaceutical company to assist in the continuing development of CAI. The government will provide all relevant available expertise and information to date and will jointly pursue new trials as required giving the pharmaceutical company exclusive rights to all preclinical and clinical data for regulatory approval and its New Drug Application (NDA). The successful pharmaceutical company will provide the necessary quantities of drug plus the necessary financial and organizational support to complete further development of CAI to establish clinical efficacy and possible commercial status.

The expected duration of the CRADA will be three (3) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. The government has data for the bulk production of clinical grade CAI. The successful pharmaceutical company will be allowed access to this data.

2. The government will provide data concerning pharmaceutical manufacturing and controls, including dosage form development data for the finished product.

3. The government will allow the pharmaceutical company to review and cross-file the NCI's IND.

4. The government will make the NCI's IND proprietary under such circumstances and make the IND available (exclusively) to the pharmaceutical company.

5. The government will continue the clinical development of this compound under its clinical trials network in coordination with the pharmaceutical company.

6. Relevant Government intellectual property rights are available for licensing through the Office of Technology Transfer, National Institutes of Health. For further information contact Jack Spiegel, Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892; (301) 496-7735; facsimile (301) 402-0220.

The role of Merck & Co. under the CRADA will include the following:

1. Participate in the selection of the CRADA collaborator and in the development of the CRADA Research Plan.

2. Provide for the licensing of Merck intellectual property rights to the selected Collaborator as necessary for the clinical development and commercialization of CAI as an anti-cancer agent.

The role of the successful pharmaceutical company under the CRADA will include the following:

1. Provide plans to independently secure future continuing supplies of GMP produced and formulated material to assure continued collaborative clinical development of CAI.

2. Provide funds to supplement the clinical trials support contracts and offer any other necessary support to the NCI for continued collaborative clinical development of this compound. This includes both financial support as well as personnel for data management and clinical care.

3. Provide planning and support for clinical development leading to FDA approval for marketing.

Criteria for choosing the pharmaceutical company include its demonstrated experience and commitment to the following:

1. Experience in preclinical and clinical drug development.

2. Experience and ability to produce, package, market and distribute pharmaceutical products.

3. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

4. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from clinical trials of investigational agents.

5. The provision of adequate quantities of GMP produced and formulated CAI as needed for clinical development of this agent for the specified field of use to be determined upon mutual agreement of the parties.

6. Provide defined financial and personnel support for the clinical trials to be mutually agreed upon.

7. An agreement to be bound by the DHHS rules involving human and animal subjects.

8. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

9. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of

ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee(s) is (are) the sole inventor(s)) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee(s) is (are) the sole inventor(s) or where a joint invention arises).

Dated: April 13, 1995.

Thomas D. Mays,

*Director, Office of Technology Development,
OD, NCI.*

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National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement ("CRADA") for the Scientific and Commercial Development of Certain Signal Transduction Inhibitors as Anticancer Agents

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a pharmaceutical company which can effectively pursue the preclinical development and possible eventual clinical development of a family of agents which inhibit the signal transduction pathways required for the growth and metastasis of cancer cells. The National Cancer Institute has preclinical data suggesting that these agents may have potential for the treatment and/or prevention of cancer. The selected sponsor will be awarded a CRADA for the co-development of these agents in a specified field of use to be determined upon mutual agreement of the parties.

ADDRESSES: Questions about this opportunity may be addressed to Mark W. Noel, Office of Technology Development, NCI, Building 31/Room 4A51, 9000 Rockville Pike, Bethesda, Maryland 20892, (301) 496-0477, facsimile (301) 402-2117, from whom further information including a summary copy of the preclinical data may be obtained.

DATES: In view of the important priority of developing new drugs for the treatment or prevention of cancer, interested parties should notify this office in writing no later than June 26, 1995. Respondents will then be provided an additional 60 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION:

"Cooperative Research and Development Agreement" or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking a pharmaceutical company which, in accordance with the requirements of the regulations governing the transfer of Government-developed agents (37 CFR 404.8), can develop the subject agents to a marketable status to meet the needs of the public and with the best terms for the Government. These agents are a novel, chemically-defined family of agents being investigated in the Laboratory of Pathology of the Division of Cancer Biology, Diagnosis and Centers, National Cancer Institute. These agents have been demonstrated to inhibit the signal transduction pathways required for the growth and metastasis of cancer cells and have shown promising antitumor activity in preclinical investigations. The majority of the agents which are the subject of the CRADA opportunity are the subject of patent U.S. Patent 5,359,078 which is assigned to the Dept. of Health and Human Services. A method for the detection and quantitation of the levels of these agents in blood is claimed in U.S. Patent 5,405,782 which is also assigned to the Dept. of Health and Human Services. The Cooperative Research and Development Agreement ("CRADA") will allow a pharmaceutical company to provide resources, in collaboration with the NCI, for the continuing preclinical development and possibly the clinical development for this group of agents.

The government will provide all relevant available expertise and information to date and will, jointly pursue further preclinical development of these agents with the chosen Collaborator. Relevant background patent rights are available for licensing to the Collaborator.

The successful pharmaceutical company will provide the necessary quantities of the agents plus the necessary technical expertise, financial and organizational support to complete further development of these agents to establish their efficacy and possible commercial status.

The expected duration of the CRADA will be three (3) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. The government will continue preclinical development of the agents as